

### **REMARKS**

Claims 8-13, 15-22, 24-29, 31-33, 35-50, and 53-71 are pending in this application. Applicant has amended claims 8, 13, 29, 68 and 71 by this amendment. No new matter has been added.

#### **I. Claim Rejections - 35 U.S.C. §102**

Claims 8, 9, 13, 15, and 71 stand rejected under 35 U.S.C. 102(b) as being anticipated by Garrett et al. (GB 2,331,707, hereinafter "Garrett '707").

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Note that, in some circumstances, it is permissible to use multiple references in a 35 U.S.C. 102 rejection. See MPEP § 2131.01.

Claims 8 and 71 have been amended. Claim 8 has been amended to recite the feature of "said first fuel gas comprising at least one hydrocarbon fuel gas," and claim 71 has been amended to recite the feature of "ambient air intentionally supplemented with hydrogen gas." The support for the feature of claim 8 is found in the specification from page 10, line 15 to page 11, line 2. The

support for the feature of claim 71 is found in the whole specification.

Because Garrett '707 discloses only the use of the gas mixture consisting of oxygen and hydrogen, all the features of claims 8 and 71 are not found in Garrett '707.

Since each and every element as set forth in claims 8, 9, 13, 15 and 71 is not found in Garrett '707, claims 8, 9, 13, 15 and 71 are not anticipated by Garrett '707. Withdrawal of the rejection is respectfully requested.

## **II. Claim Rejections - 35 U.S.C. §103**

1. Claims 10-12, 17, 29, 32, 58-60, 61, 62, 63, 65-68, 70 were rejected under 35 U.S.C. 103(a) as being unpatentable over Garrett et al. (GB 2,331,707) (and further in view of Monnier '563 or Lake '180).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

First, since Garrett '707 discloses only the use of the gas mixture consisting of oxygen and hydrogen, Garrett '707 does not teach or suggest all the claim limitations of claims 8 and 71 as

amended. Therefore, claims 10-12, 17, 29, 58-60, 62 and 63 are not obvious because these claims depend effectively from claim 8.

Second, the examiner fails to establish a prima facie case of obviousness for the following reasons.

(1) With respect to claims 10-12 and 58-60, the examiner asserted that “the particular duration of administration of the oxygen/fuel gas mixture to a patient in Garrett et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular time period. That is, it would have been obvious to employ a time period of administration that is suitable to the particular medical needs of a given patient.”

The examiner's assertion is not proper.

First, the particular duration is not recognized as a result-effective variable for achieving the intended purpose of the present invention (i.e., the protection from the reactive oxygen species).

**“A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal/ft<sup>2</sup>. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result- effective variable.). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (prior art suggested proportional balancing to achieve desired results**

in the formation of an alloy)." See MPEP §2144.05.

Therefore, before deciding whether the particular duration might be characterized as routine experimentation, the examiner must decide whether the particular duration is first recognized as a result-effective variable, i.e., a variable which achieves **a recognized result**. If the answer to this test is yes, the examiner must then decide whether the particular duration is critical.

Here, the examiner did not decide whether the particular duration be recognized as a result-effective variable, and did decide merely that the particular duration is not critical and is characterized as routine experiment. Since Garrett '707 did not recognize that the gas mixture of hydrogen and oxygen can provide the protection from reactive oxygen species, the particular duration was neither recognized nor suggested in Garrett '707 as a variable for achieving the protection from the reactive oxygen species. (See *supra In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).)

Therefore, the examiner's rejection is not proper.

Second, alternatively, or in addition to the above first reason, Garrett '707 does not suggest the desirability of the modification.

The Court held that the mere fact that references can be combined or modified does not render the resultant combination obvious **unless the prior art also suggests the desirability of the combination or modification**. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Here, Garrett '707 stated that, since the asthma drugs take time to have an effect, it is essential during this very critical period that the lungs continue to supply oxygen to the blood stream. Garrett '707 suggested the use of the gas mixture of oxygen for asthma patients and

hydrogen and how to deliver the gas mixture to asthma patients. The most widely used medications for controlling sudden asthma attacks and for preventing attacks brought on by physical activity or exercise are believed to be bronchodilators. Bronchodilators generally start to work 15 minutes to one hour after being taken. After bronchodilators take effect, there is no desirability to continue to use the highly dangerous gas more than one hour, one day, or one month because the gas mixture of Garrett '707 is not for curing the asthma. Garrett '707 suggested only the use of the gas mixture during the critical period.

Since Garrett '707 does not suggest the desirability of the modification, withdrawal of the rejection is respectfully requested.

(2) With respect to claims 29 and 63, the examiner stated that Garrett et al. (page 2, lines 20-21) discloses the delivery and preparation of the breathable gas composition by providing the constituents (oxygen and hydrogen) to a mixing chamber within the mask (8). The examiner asserted that, "[w]hile Garrett et al. discloses the use of oxygen, it would have been obvious to modify the oxygen source to substitute ambient air to a patient that did not have a medical need for pure oxygen inasmuch as ambient air contains at least 21% oxygen.

The Court held that proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

As stated above, Garrett '707 expressly suggested the gas mixture containing between 40 to 95% by volume oxygen with the remainder being hydrogen. Since this suggested gas mixture is

highly dangerous, Garrett '707 teaches how to make the gas mixture of oxygen and hydrogen available to the patient. The examiner disregarded this suggestion or teaching. If Garrett '707 uses an ambient air rather than 40 to 95% by volume oxygen, the modified composition is less desirable compared with the mixture of oxygen and hydrogen. Accordingly, the proposed modification would render the Garrett '707 invention unsatisfactory for its intended purpose.

Since there is no suggestion or motivation to make the proposed modification, the examiner fails to establish a prima facie case of obviousness.

(3) As to claim 62, the examiner asserted that, while Garrett et al. disclose the delivery of hydrogen gas to patients, it is submitted that it would have been obvious to substitute any one of a plurality of well-known fuel gases for hydrogen including acetylene as substitution of one fuel gas for another with no new or unobvious results accruing. The examiner also asserted that, inasmuch as both hydrogen and acetylene are fuel gases, the administration of acetylene or hydrogen would have been equally effective in the treatment of patients.

MPEP §2144.06 states that, "[i]n order to rely on equivalence as a rationale supporting an obviousness rejection, **the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents.** *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958) (emphasis added). The Court also held that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Here, the examiner's rationale is based only on the applicant's disclosure. Garrett '707 teaches or suggests only the use of the gas mixture of hydrogen and oxygen. Also, Garrett '707 neither teaches nor suggests that hydrogen can be replaced with other fuel gases. The examiner's argument is based merely on the fact that hydrogen is fuel gas and on the applicant's disclosure. The examiner must provide the reason why the ordinary skilled person could use acetylene instead of hydrogen when Garrett '707 teaches the use of hydrogen, but does not teach or suggest the use of fuel gas. Furthermore, since Garrett '707 teaches that the use of the hydrogen is preferred, Garrett '707 teaches away from the replacement of hydrogen with acetylene.

Therefore, the examiner's rationale is not proper. Withdrawal of the rejection is respectfully requested.

(4) As to claim 65, the examiner asserted that, while Garrett et al. disclose the delivery of hydrogen gas to patients, it is submitted that it would have been obvious to substitute any one of a plurality of well-known fuel gases for hydrogen including acetylene as substitution of one fuel gas for another with no new or unobvious results accruing. The examiner also asserted that, inasmuch as both hydrogen and acetylene are fuel gases, the administration of acetylene or hydrogen would have been equally effective in the treatment of patients.

For the same reasons stated in response to the rejection of claim 62, claim 65 is not obvious over the prior art.

(5) As to claim 66, the examiner asserted that Garrett et al. (page 2, lines 20-21) discloses the

delivery and preparation of the breathable gas composition by providing the constituents (oxygen and hydrogen) to a mixing chamber within the mask (8). The examiner further asserted that, while Garrett et al. disclose the use of oxygen, it would have been obvious to modify the oxygen source to substitute ambient air to a patient that did not have a medical need for pure oxygen inasmuch as ambient air contains at least 21% oxygen.

As stated above, Garrett '707 teaches the gas mixture containing between 40 to 95% by volume oxygen with the remainder being hydrogen. If the Garrett '707 patent uses an ambient air rather than 40 to 95% by volume oxygen, the proposed modification would render the Garrett '707 invention being modified unsatisfactory for its intended purpose (*i.e.*, the improvement in supplying oxygen to asthma patients). Also, there is no desirability.

The examiner also stated that, when a patient that did not have a medical need uses the Garrett et al. invention, the oxygen can be substituted with ambient air. When the only utility suggested or taught by Garrett '707 is the use for the asthma patient, there is no motivation to use the Garrett '707 invention for a patient that did not have a medical need. If there is no medical need, why should the patient use the highly dangerous Garrett '707 gas mixture? Garrett '707 does not suggest the desirability of the examiner's modification.

Since there is no suggestion or motivation to make the proposed modification, the examiner fails to establish a prima facie case of obviousness.

(6) As to claims 67 and 68, the applicant stated why the independent claim 65 is patentable. Since claims 67 and 68 depend effectively from claim 65, claims 67 and 68 are also patentable.



(7) Claim 32 was rejected under 35 U.S.C. 103(a) as being unpatentable over Garrett et al. as applied to claims 10-12, 17, 29, 58-60, 62, 63, 65-68 above, and further in view of Monnier ('563).

The applicant stated why claim 29 is patentable. Since claim 32 depends from claim 29, claim 32 is also patentable.

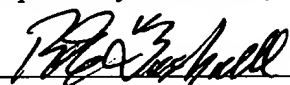
(8) Claims 61 and 70 were rejected under 35 U.S.C. 103(a) as being unpatentable over Garrett et al. in view of Lake ('180).

The applicant stated why claim 8 is patentable. Since claims 61 and 70 depend from claim 8, claims 61 and 70 are also patentable.

No fee is incurred by this Amendment. Should other fees be incurred, the Commissioner is authorized to charge Deposit Account No. 02-4943 of Applicant's undersigned attorney in the amount of such fees. Should questions remain unresolved, the Examiner is requested to telephone the Applicant's attorney.

In view of the above, all claims are deemed to be allowable and this application is believed to be in condition to be passed to issue. Reconsideration of the rejections and objections is requested. Should any questions remain unresolved, the Examiner is requested to telephone Applicant's attorney.

Respectfully submitted,

  
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Robert E. Bushnell  
Attorney for Applicant  
Reg. No.: 27,774

1522 K Street, N.W.  
Washington, D.C. 20005  
(202)408-9040

Folio: P56156  
Date: 9/3/04  
I.D.: REB/JHP